26 August 2024
302-24

Call for submissions – Application A1260

2-Methyloxolane as a processing aid

Food Standards Australia New Zealand (FSANZ) has assessed an application originally submitted by Pennakem Europa[1] to permit 2-methyloxolane as an extraction solvent processing aid and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application are to be made through the Consultation Hub (https://consultations.foodstandards.gov.au/).

All submissions on this application will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at Making a submission.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 20 September 2024

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
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[1] EcoXtract acquired Pennakem Europa following acceptance of the application by FSANZ. The applicant is now EcoXtract.

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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website[2]:

SD1 Risk and technical assessment report

[2] https://www.foodstandards.gov.au/food-standards-code/applications/Application-A1260-2-methyloxolane-as-a-processing-aid

Executive summary

EcoXtract (previously ‘Pennakem Europa’) has applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit 2-methyloxolane (2-MeOx) as an extraction solvent processing aid.

2-MeOx is proposed to be used to extract and separate oils and proteins from plant-based products, including oilseeds. It would also be used to extract other components including flavours, fragrances and colours from plant-based sources.

2-MeOx performs its technological purpose during the production of food and is not performing its technological purpose in the food for sale. It is therefore functioning as a processing aid for the purposes of the Code.

Based on FSANZ’s assessment, no public health and safety concerns were identified from the use of 2-MeOx as an extraction solvent at the following maximum permitted levels (MPLs):

- 3 mg/kg for infant formula products
- 5 mg/kg in foods for infants and formulated supplementary foods for young children, and
- 20 mg/kg for other foods.

Following assessment, for reasons set out in this report, FSANZ has prepared a draft variation to amend Schedule 3 and the table to section S18—8 of the Code. The draft variation, if approved, would permit 2-MeOx to be used as an extraction solvent processing aid in food in accordance with the Code. The permission would be subject to the condition that 2-MeOx must not be present in the food at a level greater than the corresponding MPL indicated in the table to section S18—8.

In addition, if approved, the draft variation would insert specifications setting out specific identity and purity requirements for 2-MeOx in Schedule 3 of the Code, with which the processing aid would have to comply (in addition to the specifications in section S3—4 regarding limits for arsenic and other heavy metals).

FSANZ now seeks submissions on the draft variation.

1 Introduction

1.1 The applicant

The application was originally submitted by Pennakem Europa, a subsidiary of the Minafin Group. On 26 April 2024, EcoXtract acquired Pennakem Europa. FSANZ received notification that EcoXtract was now the applicant for A1260 on 31 July 2024. From their website[3], EcoXtract is a company that develops and produces renewable, bio-sourced extraction solvents.

1.2 The application

The purpose of the application is to amend the Australia New Zealand Food Standards Code (the Code) to permit 2-methyloxolane (2-MeOx) for use as an extraction solvent processing aid.

2-MeOx would be used to extract and separate oils and proteins from plant-based products, including oilseeds. It would also be used to extract other components including flavours, fragrances and colours from plant-based sources.

2-MeOx performs its technological purpose during the production of food and not in the food for sale, therefore functioning as a processing aid for the purposes of the Code.

2-MeOx is produced from agricultural by-products including corn cobs, sugarcane bagasse and rice straw. The applicant proposes that 2-MeOx can be used as an alternative to hexane, which is a permitted extraction solvent worldwide.

The application requested the following maximum permitted levels (MPL) for residual 2-MeOx in foods:

- 5 mg/kg in infant formula products
- 5 mg/kg in foods for infants, and
- 20 mg/kg in other foods.

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

1.3.1 Permitted use

Paragraph 1.1.1—10(6)(c) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance used as a processing aid unless the use of that substance as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance ‘used as a processing aid’ in relation to a food is a substance used during the course of processing that meets all of the following conditions:

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale, and
- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at Good Manufacturing Practice (GMP).

[3] https://ecoxtract.com/

Standard 1.3.3 and Schedule 18 list the permitted processing aids. Section 1.3.3—10 permits substances listed in the table to section S18—8 to be used as processing aids to perform the technological purpose of an extraction solvent if the substance concerned is used in relation to a food listed in the corresponding row of the table, and is not present in the food at a level greater than the MPL specified in the corresponding row of the table. 2-MeOx is not listed in the table to S18—8 and so is not currently a permitted extraction solvent processing aid for use in food processing.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids in food to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code.

Schedule 3 includes a number of primary and secondary sources of specifications at S3—2 and S3—3 respectively. Where a substance does not have a relevant identity and purity specification within these sources, as is the case for 2-MeOx, then a new specification must be included in this Schedule.

In addition, S3—4 contains additional and supplementary requirements relating to limits for arsenic and other heavy metals. If permitted, 2-MeOx would also be required to comply with these requirements.

1.3.3 Labelling requirements

Subsection 1.1.1—10(8) provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

1.4 International and overseas standards

1.4.1 International

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). In contrast to food additives, there is no Codex ‘general standard’ for processing aids.

However, there is a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010), which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP.

1.4.2 European regulations

Commission Directive (EU) 2023/175[4], dated 26 January 2023, authorised the use of 2-MeOx as an extraction solvent in the production or fractionation of fats, oils or cocoa butter; preparation of defatted protein products and defatted flours; and preparation of defatted cereal germs (Table 1).

[4] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023L0175

Table 1 **Commission Directive (EU) 2023/175 – conditions of use for 2-MeOx**

Name	Conditions of use (summary description of extraction)	Maximum residue limits in the extracted foodstuff or food ingredient
2-methyloxolane	Production or fractionation of fats and oils and production of cocoa butter	1 mg/kg in the fat or oil or cocoa butter
	Preparation of defatted protein products and defatted flours	10 mg/kg in the food containing the defatted protein products and the defatted flours
		30 mg/kg in the defatted soya products as sold to the final consumer
	Preparation of defatted cereal germs	5 mg/kg in the defatted cereal germs

The Directive also established specific purity criteria for 2-MeOx (Table 2).

Table 2 **Commission Directive (EU) 2023/175 – purity criteria for 2-MeOx**

CAS number	96-47-9
Assay	Content not less than 99,9 % expressed on dry basis
Purity	
Furan	Not more than 50 mg/kg (expressed on dry basis)
2-methylfuran	Not more than 500 mg/kg (expressed on dry basis)
Ethanol	Not more than 450 mg/kg (expressed on dry basis)

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act* (FSANZ Act), and
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application is being assessed under the General Procedure in the FSANZ Act.

2 Summary of the assessment

2.1 Food technology assessment

FSANZ has undertaken a food technology assessment to determine whether the processing aid achieves its technological purpose as described in the application (see SD1).

2-MeOx has been shown to be technologically justified for use as an extraction solvent in food. It would be used to separate and extract oils and proteins from plant sources including corn and oilseeds. It would also be used to extract natural aroma, flavours and colorants, particularly those that are lipophilic (e.g. hops, annatto, carotenoids and chlorophyl).

2-MeOx performs its technological purpose during the production of food and is not performing its technological purpose in the food for sale. It is therefore functioning as a processing aid for the purposes of the Code.

2.2 Risk assessment

FSANZ has assessed the public health and safety risks associated with 2-MeOx and its proposed use as a processing aid. A summary of this risk assessment is provided below.

2-MeOx has been used in pharmaceutical production since 2007.

Toxicokinetic studies in rats and mice show that 2-MeOx is rapidly absorbed and excreted in these species and does not accumulate in any organ.

A range of *in vitro* and *in vivo* genotoxicity assays, including bacterial reverse mutation assays, mammalian gene mutation tests, micronucleus tests and a chromosomal aberration test, have been conducted. Collectively, these support the conclusion that 2-MeOx does not show genotoxic potential.

Long-term carcinogenicity studies are not required because 2-MeOx is not genotoxic and no lesions likely to lead to neoplasia by a nongenotoxic mechanism were observed in the three-month repeat-dose study conducted in rats. No case reports of allergy or intolerance attributable to oral exposure to 2-MeOx were located. From the lowest No Observed Adverse Effect Level (NOAEL) identified in animal studies, 100 mg/kg bw/day, FSANZ derived an acceptable daily intake (ADI) of 1.0 mg/kg bw/day.

The applicant requested an MPL for residual 2-MeOx of 20 mg/kg in foods, with the exception of infant formula products and foods for infants, where a MPL of 5 mg/kg was requested.

Dietary exposure assessments (DEA) were conducted to capture all the foods/food groups requested and the different MPLs requested. The DEA covered populations in Australia and New Zealand including infants under 12 months. The dietary exposure to residual 2-MeOx from general purpose foods (including formulated meal replacements and formulated supplementary foods) at 20 mg/kg of 2-MeOx was estimated to be approximately 65% of the ADI.

When used at the requested MPL of 5 mg/kg, DEAs found the estimated 90th percentile exposure to 2-MeOx to exceed the ADI of 1 mg/kg bw/day for infants aged 3 months and exclusively infant formula-fed. As a result of this, FSANZ has concluded that the MPL for infant formula products should be reduced from 5 mg/kg to 3 mg/kg.

During the assessment FSANZ sought confirmation from the applicant on the MPL they were requesting for formulated supplementary foods for young children (FSFYC) regulated under Standard 2.9.3 of the Code. The applicant requested that it be aligned with the MPL proposed for foods for infants (i.e. 5 mg/kg) (Table 3).

Table 3 2-MeOx MPLs considered for different food categories

Food Category	Age	Proposed by applicant 2-MeOx (mg/kg)	Draft variation 2-MeOx (mg/kg)
Infant formula products (includes infant formula, follow on formula and infant formula products for special dietary use)	under 12 months	5	3
Foods for infants	under 12 months	5	5
Formulated supplementary foods for young children	1 to 3 years	5*	5
Other food	N/A	20	20

*FSANZ sought confirmation from the applicant during the assessment; it was aligned with the MPL for foods for infants.

For infants aged 3 months, the estimated mean and 90th percentile (P90) dietary exposures to residual 2-MeOx from only infant formula at an MPL of 3 mg/kg of 2-MeOx are 40% and 80% of the ADI respectively. It was estimated that infants aged 9 months could consume up to 1447 g of food for infants (at 5 mg/kg of 2-MeOx), or up to 2894 g of general purpose foods (at 20 mg/kg of 2-MeOx), in addition to 555 g of follow on formula (at 3 mg/kg of 2-MeOx) per day before exceeding the ADI. Infants aged 12 months could consume up to 1500 g of food for infants (at 5 mg/kg of 2-MeOx), or up to 3000 g of general purpose foods (at 20 mg/kg of 2-MeOx), in addition to 420 g of (FSFYC) per day (at 5 mg/kg of 2-MeOx) before exceeding the ADI. These amounts were well above estimated or actual food consumption amounts reported.

Dietary exposure to 2-MeOx was assessed for food for special medical purposes (FSMP). The assessment for one category of FSMP, namely very low energy diet (VLED) products, is captured within the conservative assessment for general foods based on a concentration of 20 mg/kg, for which no safety concern associated with the use of 2-MeOx was identified. For the other category, FSMP that are not very low energy foods (referred to as other FSMP in the SD1), estimated dietary exposures to residual 2-MeOx at an MPL of 20 mg/kg for adults and children are 60% and 100% of the ADI respectively. These estimates, however, are overestimates given the conservative assumptions used in the calculation. For instance, it was assumed that all other FSMP contain 2-MeOx at the proposed MPL (20 mg/kg).

Based on the safety and dietary exposure assessments, no public health and safety concerns were identified in the assessment of 2-MeOx as an extraction solvent at the proposed MPLs.

2.3 Risk management

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code permitting the use of 2-MeOx as a processing aid for the purpose of solvent extraction in relation to food. If approved, the permission would be subject to the condition that residual amounts of 2-MeOx must not be present in the food at levels greater than the corresponding MPLs specified in the table to section S18—8.

2-MeOx would also have to comply with relevant specifications specified in Schedule 3.

The conclusions from the risk and technical assessment were that the proposed use of 2-MeOx is technologically justified and there were no safety concerns associated with its use at the proposed MPLs (refer Table 3).

These and other risk management considerations for this application relating to nomenclature and labelling are discussed further below.

2.3.1 Regulatory approval for processing aids

As stated above, FSANZ has prepared a draft variation to permit the proposed use of 2-MeOx as a processing aid – to be used as an extraction solvent in food. The express permission would also provide the permission for residual amounts to be present in the food for sale at levels no greater than the proposed MPLs (see section 2.2 above).

2.3.2 Nomenclature

For the purposes of the Code, FSANZ has proposed the name 2-methyloxolane. This is consistent with the applicants' request and its IUPAC[5] identifiers of either 2-methyloxolane or 2-methyltetrahydrofuran (see Table 1 of SD1). The Therapeutic Goods Administration (TGA) has not established an Australian Approved Name (AAN) for this substance at this time.

2.3.3 Maximum permitted levels

As described in section 2.2 of this report, this application requested 2-MeOx be *used as a processing aid* in all foods at an MPL of 20 mg/kg, with the exception of infant formula products, foods for infants and formulated supplementary foods for young children (5 mg/kg). Due to the estimated exceedance of the ADI for infants at the proposed MPL, the draft variation instead prescribes a lower MPL of 3 mg/kg for infant formula products. At the lower MPL of 3 mg/kg for infant formula products, FSANZ's DEA identified no exceedances of the ADI for infant groups considered. No other dietary exposure exceedances were identified for the foods/food groups requested (including for all categories of FSMP, which includes VLED products) at the proposed MPLs using conservative assumptions (refer section 4 of SD1).

2.3.4 Specifications

Section 1.1.1—15 requires a substance that is *used as a processing aid* must comply with any relevant specification set out in Schedule 3 of the Code.

There is no relevant specification that would generally apply to 2-MeOx in Schedule 3 of the Code (other than the specifications for arsenic and other heavy metals in section S3—4). The draft variation would insert specifications setting out specific identity and purity requirements for 2-MeOx in Schedule 3, with which the processing aid would have to comply (in addition to those in section S3—4).

Limits were established for furan, 2-methylfuran and ethanol based on the potential for these substances to be present due to the manufacturing process and that among the impurities present in 2-MeOx preparations, furan and 2-methylfuran were those of the highest hazard. The specifications for these impurities are consistent with those listed in Commission Directive (EU) 2023/175 (see Table 2 of this report).

If 2-MeOx is permitted, the individual specification for 2-MeOx for inclusion in Schedule 3 is shown in Table 4.

[5] International Union of Pure and Applied Chemistry

Table 4 Specification for 2-MeOx proposed by FSANZ

Physical and chemical parameters	Specification
Chemical name	2-Methyloxolane
Chemical formula	$C_5H_{10}O$
CAS Number	96-47-9
Purity (on a dry weight basis)	not less than 99.9%
Ethanol (on a dry weight basis)	not more than 450 mg/kg
Furan (on a dry weight basis)	not more than 50 mg/kg
2-methylfuran (on a dry weight basis)	not more than 500 mg/kg

The specification will apply to the applicant's 2-MeOx and to 2-MeOx produced by other manufacturers. That is, other parties will be able to manufacture 2-MeOx and can develop processes to use 2-MeOx in the manufacture and processing of food products. However, all manufacturers/suppliers will be required to comply with the requirements listed in the specification for 2-Me-Ox in Schedule 3 when it is added to food in accordance with the Code, or sold for use in food as a processing aid.

As mentioned above, section S3—4 contains additional MPLs for arsenic and heavy metals for any substance, including 2-MeOx:

- 2 mg/kg of lead; or
- 1 mg/kg of arsenic; or
- 1 mg/kg of cadmium; or
- 1 mg/kg of mercury.

2.3.5 Labelling

Relevant labelling provisions in the Code will apply to food for sale that is manufactured using this processing aid (see section 1.3.3 above).

2.3.6 Risk management conclusion

The risk management conclusion is to permit this extraction solvent, with the listed name '2-methyloxolane', as a processing aid to extract and separate oils and proteins from plant-based products, including oilseeds. It would also be used to extract other components including flavours, fragrances and colours from plant-based sources. If approved, the extraction solvent would be listed in the table to section S18—8 of the Code, which includes processing aids that perform the technological purpose of an extraction solvent.

The express permission for the extraction solvent to be used as a processing aid in Schedule 18 of the Code would also provide the permission for residual amounts to be present in the food for sale at levels no greater than the corresponding MPLs specified in the table to section S18—8 as follows:

- 3 mg/kg (Infant formula products)
- 5 mg/kg (Foods for infants)
- 5 mg/kg (Formulated supplementary foods for young children) and
- 20 mg/kg (All other foods).

An individual specification for 2-MeOx will be included in Schedule 3 to ensure that there are relevant specifications for 2-MeOx in the Schedule (in addition to specifications in section S3—4), with which the substance would have to comply.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media channels and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received from this call for submissions.

2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

As noted in section 1.4 of this report, the relevant international standard setting body is Codex. However, there is no Codex 'general standard' for processing aids. 2-MeOx has been authorised for use in the EU under Commission Directive (EU) 2023/175, dated 26 January 2023. In addition, the applicant has advised they are planning to seek approval for the use of 2-MeOx from the United States Food and Drug Administration.

As noted in section 2.3.3 of this report, the draft variation prescribes different MPLs for 2-MeOx in several categories of food, which are generally higher (i.e. less restrictive) or comparable with limits permitted in the EU, with the exception of defatted soya products as sold to the final consumer (see Table 1 of this report). Therefore, FSANZ is of the view that amending the Code to permit the use of 2-MeOx as an extraction solvent processing aid is unlikely to have a significant effect on international trade.

Regardless, FSANZ has decided to prepare a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement to enable other WTO members to comment on any proposed amendments.

2.5 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

Changes to Office of Impact Analysis requirements

Changes have been made to the Impact Analysis requirements by the Office of Impact

Analysis (OIA)[6]. Impact analysis no longer must be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for the applications relating to processing aids. This is because applications relating to permitting the use of processing aids that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved. Under this approach, FSANZ's assessment is that a RIS is not needed for this application.

Consideration of costs and benefits to meet FSANZ Act requirements

FSANZ, however, has considered the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government and industry is likely to benefit, on balance, from a move from the *status quo* (where the status quo is rejecting the application). This analysis considers permitting the proposed use of 2-MeOx as an extraction solvent processing aid in relation to food.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measure. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting 2-MeOx to be used as a extraction solvent processing aid.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

Costs and benefits of permitting the proposed use of 2-MeOx

In FSANZ's view, the likely benefits of the proposed amendments to the Code (if the draft variation is approved) would outweigh the likely costs.

The food industry may benefit if the draft variation is approved. 2-MeOx as a processing aid for the purpose of solvent extraction has different properties to other extraction solvents, some of which may be advantageous to food manufacturers under certain circumstances. The permission would be voluntary, therefore manufacturers would only use 2-MeOx where a commercial net benefit exists for them.

Consumers may benefit from the application being approved, where improvements in manufacturing processes result in products that better meet consumer demand, or where cost savings from manufacturers are passed on to consumers.

Permitting the proposed use of this extraction solvent may result in a small, inconsequential cost to government in terms of an addition to the current range of processing aids that are already monitored for compliance.

[6] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting 2-MeOx to be used as a processing aid for the purpose of solvent extraction would most likely outweigh any costs.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied because of the application.

2.5.1.3 Any relevant New Zealand standards

The standards in the Code that are relevant to the permitted use of processing aids apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

FSANZ undertook a risk and technical assessment (see SD1) and concluded there were no public health and safety concerns associated with permitting the proposed use of 2-MeOx as a processing aid for the purpose of solvent extraction.

2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Existing labelling requirements will apply to 2-MeOx in accordance with the Code to enable consumers to make informed choices (see sections 1.3.3 and 2.3.5 of this report).

2.5.2.3 The prevention of misleading or deceptive conduct

There are no issues identified for this application relevant to this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application.

- **the promotion of consistency between domestic and international food standards**

2-MeOx was recently added to the list of permitted solvents for production of foodstuffs and food ingredients in Europe (Directive 2009/32/EC) (Commission Directive (EU) 2023).

- **the desirability of an efficient and internationally competitive food industry**

Australia and New Zealand would remain competitive with other international markets, where authorisation for the use of the 2-MeOx as an extraction solvent in food is already in place (Europe) or occurs in the future. This would also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment is that there are no public health and safety concerns associated with the proposed use of 2-MeOx as a processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of 2-MeOx for the applications proposed by the applicant.

Ultimately, the domestic food industry will make their own economic decisions, considering the costs and benefits of using the new processing aid, to determine if it is of benefit to their business.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[7] includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that permitting the proposed use of 2-MeOx as an extraction solvent would be consistent with these specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

[7] https://www.foodregulation.gov.au/resources/publications/policy-guideline-addition-substances-other-vitamins-and-minerals

4 References

Commission Directive (EU) 2023/175 of 26 January 2023 amending Directive 2009/32/EC of the European Parliament and of the Council as regards 2-methyloxolane. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023L0175

European Food Safety Authority (EFSA) Panel on Food Contact Materials, Enzymes and Processing Aids (2022) Safety assessment of 2-methyloxolane as a food extraction solvent. EFSA Journal. 20(3):7138. doi:10.2903/j.efsa.2022.7138

FAO/WHO (2006) Combined compendium of food additive specifications, Food and Agriculture Organization of the United Nations, Rome. http://www.fao.org/docrep/009/a0691e/A0691E03.htm

FCC (2022) Food Chemicals Codex, 13th edition. Rockville (MD): United States Pharmacopeial Convention, http://publications.usp.org/

Attachments

A. Draft variation to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

Attachment A – Draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1260 – 2-Methyloxolane as a processing aid) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert name and position title of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is *the Food Standards (Application A1260 – 2-Methyloxolane as a processing aid) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 3—Identity and purity

[1] Subsection S3—2(2) (table, before the table item dealing with 'Nicotinamide riboside chloride')

Insert:

2-Methyloxolane	section S3—52

[2] After section S3—51

Insert:

S3—52 Specification for 2-Methyloxolane

For 2-Methyloxolane, the specifications are the following:

(a) chemical name—2-Methyloxolane;
(b) chemical formula—$C_5H_{10}O$;
(c) CAS Number—96-47-9;
(d) purity (on a dry weight basis)—not less than 99.9%;
(e) ethanol (on a dry weight basis)—not more than 450 mg/kg;
(f) furan (on a dry weight basis)—not more than 50 mg/kg;
(g) 2-methylfuran (on a dry weight basis)—not more than 500 mg/kg.

Schedule 18—Processing aids

[3] Section S18—8 (table, before the table item dealing with 'Propane')

Insert:

2-Methyloxolane	Infant formula products	3
	Foods for infants	5
	Formulated supplementary foods for young children	5
	All other foods	20

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1260 – 2-Methyloxolane as a processing aid) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1260 which seeks to amend the Code to permit 2-methyloxolane (2-MeOx) as a processing aid for the purpose of an extraction solvent in relation to food. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1260 – 2-Methyloxolane as a processing aid) Variation*.

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers' Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared a draft variation amending the table to section S18—8 of the Code to permit the use of 2-MeOx as a processing aid for the purpose of being an extraction solvent in relation to food. 2-MeOx would be used to extract and separate oils and proteins from plant-based products, including oilseeds. It would also be used to extract other components including flavours, fragrances and colours from plant-based sources. This permission would be subject to the condition that 2-MeOx must not be present in the food at a level greater than the maximum permitted level indicated in the corresponding row of the table (3 mg/kg in infant formula products; 5 mg/kg in foods for infants and formulated supplementary foods for young children; 20 mg/kg in all other foods).

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1260 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a four-week period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[8]. Impact analysis no longer must be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for the applications relating to processing aids. This is because applications relating to permitting the use of processing aids that have been determined to be safe are minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved. Under this approach, FSANZ's assessment is that a RIS is not required for this application.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003.*

7. Variation

References to 'the variation' in this section are references to the draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1260 – 2-Methyloxolane as a processing aid) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation commences on the date of gazettal of the instrument.

[8] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

Schedule to the variation

Items [1] and [2] of the Schedule to the variation would amend Schedule 3 of the Code.

Schedule 3 contains specifications for the purposes of section 1.1.1—15 of the Code. Section 1.1.1—15 requires certain substances, e.g. substances used as processing aids, to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code, or sold for use in food.

Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)). This table lists entries consisting of substances for which there are specifications in Schedule 3 (column 1); and their associated provisions (column 2).

Item [1] would amend the table to subsection S3—2(2) by inserting a new entry into the table before the table item dealing with 'Nicotinamide riboside chloride'. The new entry consists of '2-Methyloxolane' in column 1 of the table and 'section S3—52' in column 2 of the table.

This amendment is consequential to the amendment proposed in **item [2]** (see below).

Item [2] would insert new section S3—52 into Schedule 3, which sets out identity and purity specifications specifically for 2-MeOx.

If the variation is approved, the effect of amendments proposed in **items [1]** and **[2]** would be that when 2-MeOx is added to food in accordance with the Code, or sold for use in food, 2-MeOx would have to comply with the new specification in section S3—52, in addition to any other relevant specification in Schedule 3.

Item [3] of the Schedule to the variation would amend Schedule 18 of the Code.

Schedule 18 lists substances that may be used as processing aids for the purposes of the Code.

In particular, **item [3]** would insert a new entry into the table to subsection S18—8 of the Code. This table lists substances that are permitted to function as extraction solvents for the purposes of section 1.3.3—10 of the Code.

According to section 1.3.3—10, a substance listed in section S18—8 may be used as a processing aid to perform the technological purpose of an extraction solvent if the substance satisfies both of the following conditions – the substance:

- is used in relation to a food listed in the corresponding row of the table; and
- is not present in the food at a level greater than the maximum permitted level specified in the corresponding row of the table.

The term 'used as a processing aid' is defined in section 1.1.2—13 of the Code.

Th new entry would be inserted into the table to subsection S18—8 before the table item dealing with 'Propane'; and consist of the following:

'2-Methyloxolane' is the substance listed in column 1 of the table.

The associated foods for this substance are listed in column 2 of the table as 'Infant formula products', 'Foods for infants', 'Formulated supplementary foods for young children' and 'All other foods'.

The maximum permitted level corresponding to each food is set out in column 3 of the table as follows:

- 3 mg/kg (Infant formula products);
- 5 mg/kg (Foods for infants);
- 5 mg/kg (Formulated supplementary foods for young children); and
- 20 mg/kg (All other foods).

If approved, the amendment proposed in **item [3]** would permit the proposed use of 2-MeOx as a processing aid in accordance with the Code.